

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of
CHANG et al.

Serial No: 10/685,941

Filed: October 14, 2003

For: COMBINATION OF BRIMONIDINE
AND TIMOLOL FOR TOPICAL
OPHTHALMIC USE

Group Art Unit: 1614

Examiner: Brian S. Kwon

Confirmation No. 7685

**DECLARATION OF AN EXPERT REGARDING FACTS RELEVANT TO
PATENTABILITY (37 C.F.R. § 1.132)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PURPOSE OF DECLARATION

1. This declaration is to establish evidence of patentability of one or more claims of the above referenced application.
2. The person making this declaration is an employee of Allergan, Inc, and is an expert in following the commercial success of pharmaceutical products.
3. The purpose of this declaration is to show commercial success of the claimed product.

TESTIMONY OF COMMERCIAL SUCCESS

4. Topical ophthalmic brimonidine is available as a single drug topical ophthalmic product in the countries shown in Table 1 and in the following countries: Turkey, Egypt, Jordan, Kuwait, Lebanon, Saudi Arabia, United Arab Emirates, United States, Puerto Rico, Korea, China, Malaysia, Philippines, Singapore, and Thailand. Topical ophthalmic brimonidine has been available since at least quarter 3 of 2001 in all of these countries except Poland and Jordan, where it has been on the market since quarter 4 of 2001.
5. A topical ophthalmic product has recently been introduced which contains a combination of 0.2% brimonidine and 0.5% timolol in a single composition. Worldwide, the product has been introduced into the countries indicated in Table 1 during the quarter indicated in Table 1.

Country	Launch Quarter
Canada	Q3/03
Brazil	Q2/04
Australia	Q2/05
Switzerland	Q1/05
U.K.	Q1/05
Germany	Q4/05
Ireland	Q4/05
France	Q4/05
Mexico	Q4/05
India	Q4/05
New Zealand	Q4/05
Denmark	Q1/06
Greece	Q1/06
Argentina	Q1/06
Chile	Q1/06
Colombia	Q1/06
Czech Rep.	Q2/06
Sweden	Q2/06
Spain	Q2/06
Finland	Q3/06
Netherlands	Q3/06
Norway	Q3/06
Taiwan	Q3/06
Austria	Q4/06
Hungary	Q4/06
Poland	Q4/06
Italy	Q4/06
Belgium	Q1/07

Table 1

6. Figure 1 below depicts all sales (in actual dollars) of:

- a) topical ophthalmic products containing brimonidine as the sole drug ingredient in the countries of Table 1 (Brimonidine), and
- b) a topical ophthalmic containing 0.2% brimonidine and 0.5% timolol in the countries of Table 1 (Combination),

for the time period covering the third quarter of 2001 to the second quarter of 2007.

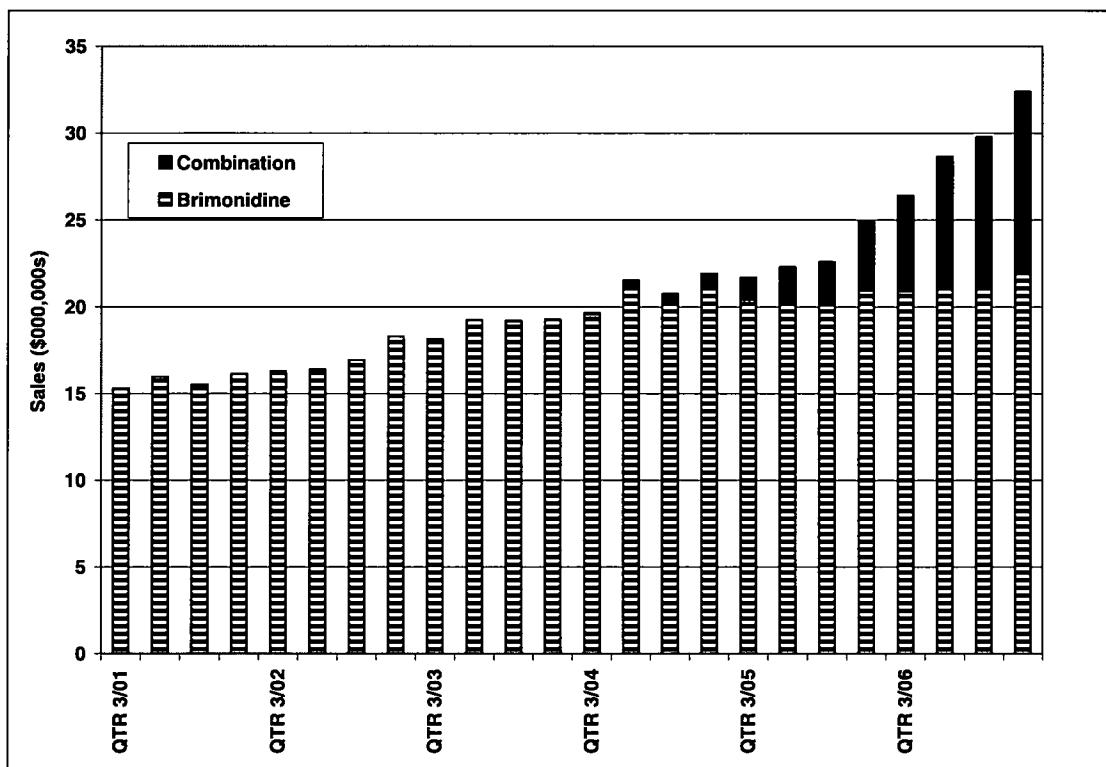


Figure 1

7. Figure 1 plainly shows that the Combination sales have steadily increased since the first launch to the present, while Brimonidine sales have been roughly constant or increased slightly.
8. Appendix 1 contains the detailed information used to generate Figure 1.
 - a) Table 2 contains the raw data which includes individual country sales used to generate Figure 1.
 - b) Figure 2 plots the sales for the individual countries where the Combination has been on the market for at least six quarters.

9. Examination of the data of Appendix 1 reveals that, in each country, sales of the Combination increased steadily after launch.
10. In my expert opinion, this data is strong evidence of commercial success.
11. This data was collected during the normal course of business. Allergan's practice is to collect sales data to track the commercial success of products after they are launched.

DECLARATION

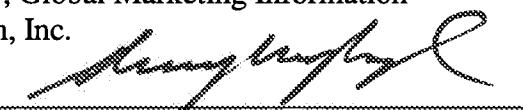
12. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

19. Person who collected data

Full name: Daryl M. Bogard, RPh, MBA
Director, Global Marketing Information
Allergan, Inc.

Expert's signature: 

Date: September 21, 2007

Country of Citizenship: USA

Residence: 19 Blessing, Irvine CA 92612

Appendix 1

	QTR 3/03	QTR 4/03	QTR 1/04	QTR 2/04	QTR 3/04	QTR 4/04	QTR 1/05	QTR 2/05	QTR 3/05	QTR 4/05	QTR 1/06	QTR 2/06	QTR 3/06	QTR 4/06	QTR 1/07	QTR 2/07	
BRAZIL			0	0	0.121	0.29	0.536	0.676	0.934	1.057	1.091	1.345	1.515	1.567	1.825		
GERMANY							0		0	0	0.27	0.919	1.151	1.326	1.397	1.575	
FRANCE								0	0	0	0.237	0.659	0.962	1.137	1.313		
CANADA	0	0	0.02	0.04	0.071	0.182	0.242	0.362	0.463	0.669	0.741	0.914	0.988	1.145	1.064	1.185	
SPAIN											0	0.039	0.535	0.8	0.965		
MEXICO											0	0.031	0.128	0.315	0.45	0.614	0.726
ITALY											0			0	0.193	0.505	
AUSTRALIA							0	0	0.053	0.168	0.179	0.239	0.29	0.349	0.306	0.388	
UK							0	0.006	0.029	0.064	0.103	0.163	0.211	0.258	0.303	0.365	
GREECE										0	0.001	0.059	0.172	0.26	0.321		
CZECH REP							0	0.015	0.057	0.103	0.122	0.168	0.172	0.092	0.157	0.191	
SWITZERLAND			0					0		0	0.003	0.032	0.051	0.082	0.15	0.187	
INDIA										0		0.052	0.106	0.137	0.129	0.196	
ARGENTINA											0		0	0.064	0.103	0.117	
NETHERLANDS											0	0.034	0.037	0.063	0.081	0.106	
COLOMBIA											0		0	0.021	0.056		
HUNGARY												0		0	0.047		
NEW ZEALAND											0	0.008	0.014	0.022	0.032		
SWEDEN												0	0	0.014	0.026		
CHILE											0	0.002	0.013	0.024	0.027	0.032	
POLAND												0		0	0.006	0.023	
IRELAND											0	0.007	0.014	0.017	0.017	0.02	
TAIWAN												0	0.001	0.007	0.019		
BELGIUM													0	0	0		
FINLAND													0	0.005	0.011	0.016	
DENMARK												0	0.005	0.012	0.014	0.015	
NORWAY												0	0	0.008	0.008		
AUSTRIA													0	0	0		

Table 2

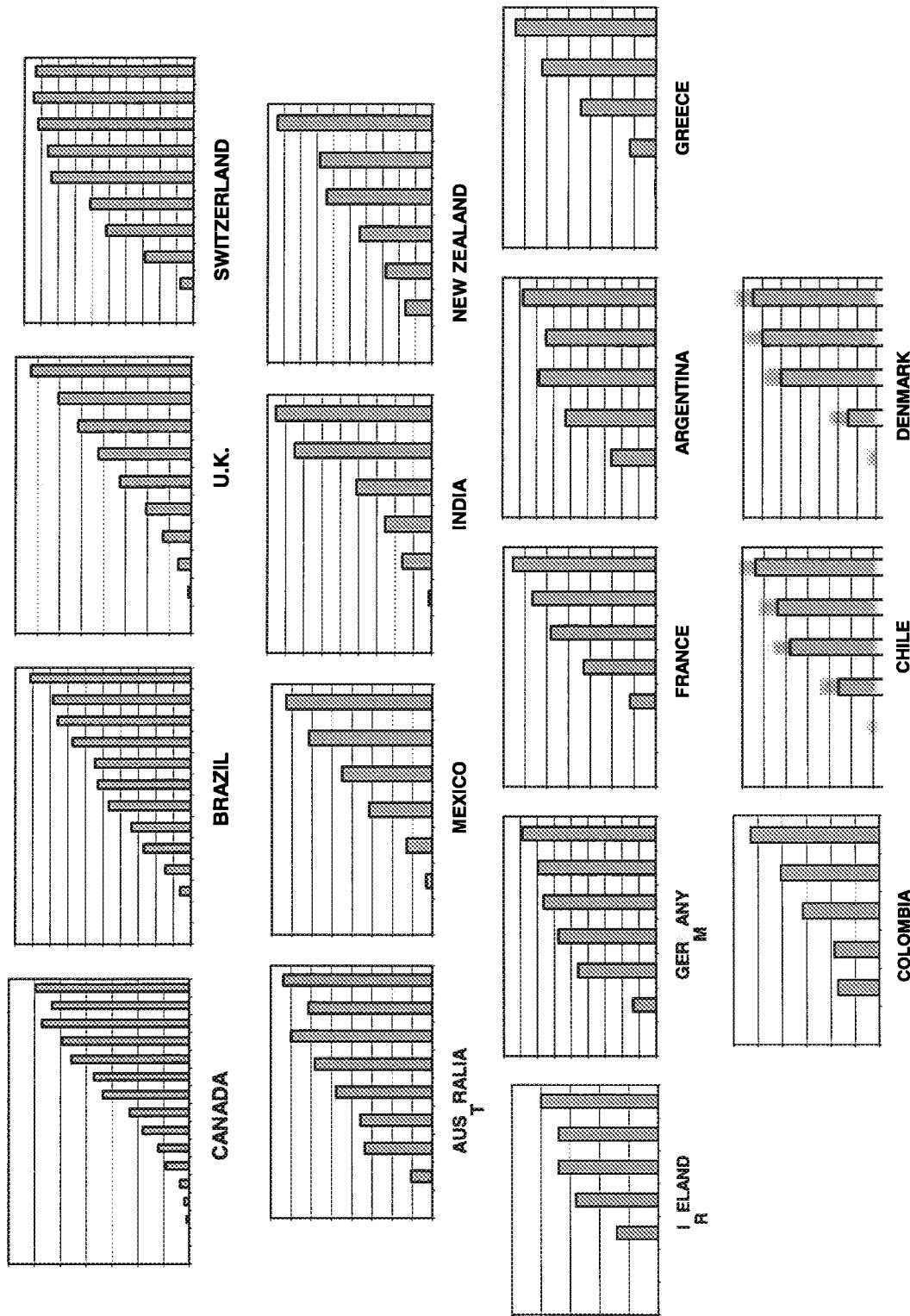


Figure 2